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EXAMINER	
MELLON, DAVID C	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,703	STORR ET AL.	
	Examiner	Art Unit	
	DAVID C. MELLON	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-26, 35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708) and in view of Pitt et al. (USP 5,037,656).

Regarding claims 1, 3-11, 13-14,16-24, 26, 35, and 39, Horl et al. discloses a process for grafting of polymers and polymers obtained thereby (Title) comprising:

- Providing a solid substrate having a substrate surface wherein amino functional groups are coupled to the substrate surface and formed as a membrane or fibers (C5/L10-20 – substrate, specifically "polyamides", C5/L40-45 – primary amino groups which are biocompatible, C7/L1-19 - fibers, membranes);
- Covalently coupling the amino functional groups with a reducing agent (C8/L1-15, C11/L28-33 – the reducing agent would couple covalently with the amino functional groups due to chemical attraction when exposed in an aqueous or liquid environment with the reducing agent and utilizing a thermal activation, C11/L43-50);
- Contacting the substrate surface with a solution of polymerizable monomers wherein graft copolymerization of the monomers forms a structure of adjacent functional polymer chains on the substrate surface (C6/L15-60, specifically see also C8/L2-44).

Horl et al. does not disclose the use of a thermally labile radical initiator to promote the polymer grafting process.

Pitt et al. discloses a composite porous membrane formed from a porous polymer membrane (Abstract) comprising:

- Providing a porous membrane (C3/L1-5)
- Covalently coupling a thermally labile radical initiator to the membrane (C4/L30-40 – see exemplary compounds, specifically "4,4'-azobis-(4-cyanovaleric acid)" - also see C3/L58-66)
- Contacting the substrate surface with a polymerizable monomer solution (C4/L12-28 – see exemplory monomers, see also C3/L58-67).

Horl et al. and Pitt et al. are combinable because they are concerned with the same field of endeavor, namely that of graft polymerization membrane structures.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the membrane and process of Horl et al. to use an azo compound such as 4,4'-azobis-(4-cyanovaleric acid) as a thermally labile radical initiator to promote graft polymerization as taught by Pitt et al. for the purpose of providing a more effective, rapider polymerization process to eliminate the need for additional crosslinking agents when using a functionalized substrate (see also Pitt C3/L1-11).

Regarding claims 2 and 15, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. further discloses that the nylon 6,6 support membranes are discloses as having a pore diameter of 0.2 micrometers which would be sufficient to allow the passage of blood serum (C20/L15-25, C21/L45-50).

Regarding claims 12 and 25, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of

dimethylaminopropyl acrylamide. However, Horl et al. does in fact set forth the use of monomers of acrylic and methacrylic acid (C6/L26-30) and further sets forth the use of dimethylaminopropyl methacrylamide (C6/L41-42). Accordingly, dimethylaminopropyl methacrylamide and dimethylaminopropyl acrylamide have art recognized equivalent function and properties such that they have become recognized as similar equivalents (see Galleguillos et al., USP 6361768 as evidentiary in column 6 where both are recognized as functional cationic monomers). It would have been obvious to one of ordinary skill in the art at the time of the invention to use dimethylamionpropyl acrylamide instead of dimethylaminopropyl methacrylamide as the art recognizes the equivalence of the two compounds and the selection of any known equivalent would have been within the level of ordinary skill in the art.

5. Claims 27-30, 32, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Bell et al. (USP 6,774,102).

Regarding claims 27-29 modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of the separating material as for endotoxin removal from blood or affinity adsorption applications.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Horl et al. as a hollow fiber or bead for removal of endotoxins via affinity adsorption as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claim 30, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of the separating material as beads in a separating column.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45). Bell et al. further discloses packing the beads into polycarbonate columns for blood purification (C7/L15-40).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Horl et al. as a bead for removal of endotoxins via affinity adsorption in a separation column as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claims 32 and 36, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. further discloses the membrane is fibrous (C7/L1-15).

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber polymer(C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the fiber based separation material of Horl et al. and form hollow fiber membranes as taught by Bell et al. for the purpose of blood filtration.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), in view of Bell et al. (USP 6,774,102), and further in view of Duggins (USP 4,668,399).

Regarding claim 31, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly disclose a separating cartridge with a tube, and potting hollow fibers in it.

Duggins discloses a hollow fiber plasmapheresis module in figures 1-3 comprising a hollow fiber membrane module (14) which is shown in figure 3 as a tube with hollow fibers in it. Furthermore, it is well known that in hollow fiber membrane modules, the fibers are potted to secure them.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the hollow fiber membrane of modified Horl et al. in a hollow fiber membrane module as taught by Duggins for the purpose of plasmapheresis.

7. Claims 33-34, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Steuck (4,618,533).

Regarding claims 33-34 and 37-38, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of copolymers that are hydrophilizing.

Steuck discloses a composite porous membrane formed from a porous polymeric membrane (abstract) which is exposed to a monomer and an initiator (C3/L45-66) wherein hydrophilizing copolymers are utilized as the substrate (C2/L60-C3/L11).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of thermally labile polymer radical grafting.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the polymer membrane of Horl et al. such that the substrate is formed from a hydrophilic copolymer as taught by Bell et al. for the purpose of improving the separation capacity and increasing the water affinity.

Response to Arguments

8. Applicant's arguments filed 6/17/2009 have been fully considered but they are not persuasive.

9. In response to applicant's argument that Horl and Pitt are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the

claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the two references are both in fact concerned with grafting based polymerization and furthermore, the instant specification/application is clearly concerned with grafting polymerization process.

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the two references are both in fact concerned with grafting based polymerization. Furthermore, as evidenced by applicant's instant specification (see excerpted below), US 5556708 is in fact a process which utilizes radicals for free radical polymerization wherein the radicals are formed using reducing agents which a type of which are well known to be acids. Additionally, Pitt et al. sets forth a process for free radical polymerization (C4/L50-60, Pitt). Accordingly, the two processes are understood by the Examiner based upon the reference's explicit and implicit disclosure and that of the applicant's disclosure as clearly analogous and combinable arts.

The US-A-5,556,708 describes a method for the production of an adsorption material by graft polymerization of a nitrogen-containing polymer with an ethylenically unsaturated monomer in an aqueous environment in the presence of two reactants, said two reactants consisting of carbon tetrachloride and a reducing agent, selected from sodium dithionite, rongalite, hydrazine, and ascorbic acid. According to the description and the examples of US-A-5,556,708, sodium dithionite seems to be the only one reducing agent that had been tested. Also, even though it is claimed that the nitrogen-containing polymer may be selected from polyamides, polysulfonamides, polyurethanes, and polymers having primary and secondary amine groups in a side chain, only a polyamide membrane, particularly a nylon 6,6 membrane, had been tested in the examples as the nitrogen-containing polymer. US-A-5,556,708 leaves unclear whether and how the method may work with a nitrogen-containing polymer having primary and secondary amine groups. It is known that amides form radicals with the reducing agents used according to US-A-

- Applicant alleges that Pitt's method uses radical initiators to form radicals to initiate the polymerization reaction which allegedly teaches away from Horl. Furthermore, Applicant alleges that radicals are oxidizing agents and thus would teach away from the required reducing agent of Horl.

The Examiner respectfully disagrees with Applicant's assertion. First, as clearly evidenced by Applicant's own specification as excerpted above, it is readily apparent to one of skill in the art that the mechanism of Horl is adequately understood since it is clearly noted by Applicant that Horl uses the reducing agent as a radical initiator ("It is known that amides form radicals with the reducing agents..."). Accordingly, since both Pitt and Horl are clearly using radical initiators and the instant claim requires radical initiators, the references are both combinable and both clearly obviate the instant claims. Applicant's remarks regarding radicals being oxidizing agents are both not commensurate with the claim scope and further not commensurate with the discussion

of Horl requiring a reducing agent. Clearly, the reducing agent of Horl has been established to form the radicals or in terms of the instant claims, the reducing agent can be considered the radical initiator. Regarding the allegation that radicals are oxidizing agents, this assertion is factually incorrect. Radicals can be either depending on the specific stoichiometry. In free radical polymerization, the radical donates the electron when the double carbon bond is broken; accordingly, this is considered an oxidation-reduction reaction because the radical is causing both processes to occur. First, the radical donates an electron which causes the break of the carbon double bond, then, the radical bonds with a free electron and leaves a free electron as a radical. Thus, the radical causes both aspects of the red-ox reaction to occur.

- Applicant alleges Horl expressly teaches away from using radical initiators to start the polymerization reaction due to the fact that Horl teaches grafting should take place at a "sharply defined position of the base polymer...".

The Examiner respectfully disagrees. See above discussion involving applicant's own admission of the teachings of the prior art and that the reducing agents of Horl form radicals.

- Applicant alleges that Horl requires the use of carbon tetrachloride and that this requirement would preclude medical uses.

The Examiner respectfully disagrees. Carbon tetrachloride may be non-optimal or undesired for medical use, however, explicitly "medical use" is not claimed. Applicant's claim recitations towards blood purification does not constitute a claim to

medical use. Merely it claims using the material for purifying blood. This may or may not be medical use. Accordingly, this argument is clearly not commensurate with the scope of the instant claims.

- Applicant alleges that the combination of Horl and Pitt does not disclose covalently coupling the radical initiator to the amino functional group.

The Examiner respectfully disagrees. The claims at issue do not require the radical initiator molecules to act as "a link or bridge between the nitrogen of the amino-functional groups and the monomer compound". Additionally, the combination of Horl and Pitt provides for the radical initiator in solution with the amino-functional and the monomer. Accordingly, there would be an inherent covalent bonding occurring between the radical initiator and then the radical with the amino group and then linking it to the monomer. Furthermore, there is clearly no other form of bonding occurring since Horl and Pitt make no mention and further there would be no ionic bonding occurring. Furthermore, Applicant's claims do not require all the amino-functional groups to covalently couple with the radical initiator, nor do they preclude any other covalent coupling from occurring simultaneously. The mere fact that Horl does not disclose in entirety the reaction mechanism does not preclude one skilled in the art from contemplating and carrying out modifications to the process of Horl. Absent a showing of evidence or unexpectedly good results, Applicant has not provided sufficient evidence of patentability.

- Applicant's allege non-obviousness due to the presence of carbon tetrachloride in Horl.

This is non-convincing because it is not commensurate with the scope of the instant claims. Applicant is further noted that the claim language is open ended and non-limiting. Further, the argument towards covalently coupling the initiator to the nitrogen group is non-convincing because it is not required (claimed) to covalently couple the initiator to the nitrogen group.

- Applicant alleges case law supports non-obviousness due to negative results possibly occurring by modifying Horl.

Absent a showing of evidence, this argument is non-convincing. Applicant has not shown that there would be negative results by modifying Horl.

It is further noted that instant claim 1 is a product claim. While the claim is a product-by-process type claim, the prior art product, an amino-functionalized graft copolymer on a substrate is clearly well known in the prior art. Accordingly, the claim would be considered anticipated and or obvious in view of the already discussed prior art. Applicant has not provided comparative examples of the prior art to the instant claimed product. Accordingly, Applicant has not established with evidence, on the record, that the instant claimed product is in fact different and performs differently with unexpected results and/or structure occurring from the process used to make it.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 7:00am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

/D. C. M./
Examiner, Art Unit 1797